

## **Summary of the Accrediting Authority Committee Meeting February 4, 1997**

The National Environmental Laboratory Accreditation Conference (NELAC) Accrediting Authority Committee met from 9:00 am to 3:00 p.m. Eastern Standard Time on Tuesday, February 4, 1997 during the NELAC II Interim Meeting held at Bethesda, Maryland. The meeting was led by Committee Chair, Mr. John Anderson, Division Manager of the State of Illinois Environmental Protection Agency (IL-EPA). A list of action items is given in Attachment A. A list of Committee members/invited guests is given in Attachment B. A copy of the meeting's agenda is given in Attachment C.

### **INTRODUCTION**

Mr. Anderson welcomed all participants and encouraged each to participate in discussions of the meeting. Each member of the Committee introduced him/herself and briefly described professional work responsibilities affiliations.

Ms. Emily Williams, a support contractor from Research Triangle Institute (RTI), described the ground rules of the meeting and reviewed the roles of the chair, facilitator, recorder, scribe, and participants. Consensus on issues was considered to be the primary decision-making procedure, with an alternative being a vote by voting members of the Committee.

Mr. Anderson stated that the desired outcomes of the meeting were to reach consensus on key issues, to document discussions, and to develop a procedure for preparing Chapter 6 for voting at the Third Annual NELAC Meeting to be held July 28-31 in Dallas, Texas.

*The purpose of the meeting was to discuss Chapter 6 in light of comments from the NELAC Board of Directors, the NELAP Director and participants at the meeting. Of particular interest were issues of "unconditional reciprocity" and credentials of the National Environmental Laboratory Accreditation Program (NELAP) assessment team. The following items were discussed.*

- Overview of Chapter 6 -- Mr. Anderson reviewed the process required for an accrediting authority to become recognized by NELAP.
- Comments from the NELAC Director -- Mr. Anderson indicated that Ms. Jeanne Mourrain, NELAC Director, had reviewed Chapter 6 and would discuss her comments with the Committee and participants.
- Credentials of the NELAP Assessment Team -- As a result of discussions with Ms. Mourrain, credentials of the NELAP assessment team were reviewed from the standpoint of including managerial experience.

- Reciprocity -- The availability of unconditional reciprocity of NELAP laboratory accreditation among NELAP-recognized accrediting authorities is a critical issue for the success of NELAP. Because of the significance of this issue, the major portion of discussions on this topic was reserved for a joint meeting with the Policy, Program and Structure Committee that was scheduled for 3:15 p.m. on February 4.
- Other issues -- Mr. Anderson encouraged the Committee and participants to raise relevant issues for discussion at this meeting. Participants were encouraged to indicate suggested changes to the chapter by proposing specific wording, either at this meeting or in subsequent communication with the Committee.

## OVERVIEW OF CHAPTER 6

Mr. Anderson indicated that, in order to ensure compliance with ISO Guide 58 (and thus, international credibility), the current version of Chapter 6 was prepared by soliciting input from a number of people and organizations intimately involved in laboratory accreditation issues from the standpoint of compliance with ISO Guide 58. Mr. Anderson underscored the impact of ISO Guides 25 and 58 on the generation of NELAC standards and referenced Section 6.9, in which a NELAP-recognized accrediting authority is defined as an accrediting authority that has meet the requirements of NELAC. In developing the version of Chapter 6 before the Committee, the Committee's philosophy was to require NELAP-recognized accrediting authorities to meet the requirements of Chapter 6. Chapter 6 requires NELAP-recognized accrediting authorities to grant NELAP accreditation only to those laboratories meeting all the applicable standards of Chapters 1-5. Thus, accredited laboratories would meet the requirements of ISO Guides 25 and 58. Because of the importance of ensuring that NELAP-recognized accrediting authorities comply with ISO Guide 58, Mr. Anderson and the Illinois EPA have cross-referenced ISO Guide 58 section by section in Chapter 6. A copy of that cross reference spreadsheet was distributed to those in attendance at the meeting.

Mr. Anderson then proceeded with an overview of Chapter 6 and the process for an accrediting authority to become NELAP-recognized. An accrediting authority must provide specific application information to NELAP. After this information is reviewed and approved by a NELAP assessment team, the accrediting authority will receive "interim" NELAP recognition. After granting "interim recognition" to an accrediting authority, the assessment team will perform an on-site audit of the accrediting authority. If the results of the audit are satisfactory, the accrediting authority will be granted full NELAP recognition. In the event that the results of the application review or subsequent audit are such that NELAP-recognition is not granted or is revoked, the accrediting authority has the option of appealing this decision. After NELAP recognition is approved, an accrediting authority must submit an application for renewal every two years to maintain its status; however, an on-site audit is conducted only once every four years.

A suggestion was made to prepare a flow chart to describe the time frame and process requirements for achieving NELAP-recognition. The chair accepted this comment and said such

a flow chart would be prepared prior to the annual meeting in July, 1997. A question was raised about the specifics of the application form for a laboratory seeking NELAP accreditation. Mr. Anderson indicated that the elements of the application form set forth in Chapter 6 are for an accrediting authority seeking NELAP recognition. The application form for a laboratory seeking NELAP accreditation falls under the purview of Chapter 4, Accrediting Process.

### **Interim Recognition and Reciprocity**

As Chapter 6 is currently written, an accrediting authority holding either interim or full NELAP recognition is authorized to grant reciprocal accreditation to laboratories holding accreditation with other NELAP-recognized accrediting authorities. A suggestion was made to restrict the granting of reciprocity only to accrediting authorities that also had completed satisfactorily the on-site audit and had achieved full NELAP recognition. The participants then discussed another option that would allow an accrediting authority holding interim NELAP recognition to grant reciprocal NELAP laboratory accreditation if that accrediting authority is in the two-year time period awaiting the adoption of new laboratory accreditation rules or passage of additional legislation needed to bring the applicant accrediting authority into compliance with the NELAC standards. No decision was made on this issue. The Committee added this to its list of issues needing resolution prior to NELAP III.

During the course of this discussion, the “wordiness” of Section 6.2(c)(1) was pointed out. The Committee agreed that this section will be rewritten to use terms “primary” and “secondary” accrediting authority to clarify reciprocity issues. These terms have been introduced into Chapter 1, and make the functions of the two accrediting authorities involved in reciprocal accreditation much easier to define.

### **CREDENTIALS FOR NELAP ASSESSMENT TEAM**

#### **Section 6.7.1 -- NELAP Assessment Team**

##### **(b) and (c)**

Currently, Chapter 6 states that the NELAP assessment team will be composed of at least one member from the U. S. Environmental Protection Agency (USEPA) and at least one member from an operating State or Federal environmental laboratory accreditation program. When NELAP is fully implemented, members will be selected from the USEPA and from NELAP-recognized accrediting authorities. The chapter was written so that staff from the other Federal agencies, such as the Department of Defense (DOD), or USEPA Regions will not be excluded from selection as NELAP assessment team members.

Concerns were raised that the pool of qualified candidates to serve on assessment teams would be less limited if NELAC allowed third-party organizations to provide members for the NELAP assessment teams. Section 6.7.1(b) does not prohibit using third-party individuals as part of the assessment team. A suggestion was made that in order to incorporate third-party organizations, conflict-of-interest issues would need to be addressed, but NELAC should explore these

alternatives. Other concerns were raised that States would not be in favor of having third-party individuals serve on assessment teams. This issue was not resolved; the Committee agreed to examine it at a later time.

**(d)**

The current Chapter 6 requirement that a NELAP assessment team member have three years of experience auditing laboratories and one year of experience administering an accreditation program was discussed, with primary focus on the administrative requirement. The Committee considered that a member of the NELAP assessment team should understand all aspects of the accrediting process and agreed to maintain the administrative experience requirement. One individual commented that, internationally, only a few people are qualified to assess accrediting authorities for compliance with ISO Guide 58. The commenter also felt strongly that the administrative experience of audit team members also is essential to maintaining ISO Guide 58 compliance. The USEPA had expressed concerns about limiting the pool of qualified candidates for appointment to NELAP assessment teams. Therefore, a suggestion was made to maintain Section 6.7.1 (d)(1), and to rewrite sections 6.7.1(d) (2) and (3) to clarify the requirements for experience, as follows:

Each NELAP assessment team member shall:

- 1) meet the education, experience and training requirements specified in the NELAC standards for laboratory assessors;

The NELAP assessment team shall:

- 2) have at least one member with three years of experience assessing laboratories (at the minimum rate of four assessments/year) acquired within the five year period immediately preceding the appointment as a NELAP assessment team member; and
- 3) have at least one member with experience that includes at least one of the following:
  - A) registration as a Lead Assessor,
  - B) one year of experience implementing Federal or state rulemaking,  
or
  - C) one year of experience developing laboratory accrediting programs within five years preceding the appointment as a NELAP assessment team member.

The Committee concurred in this wording and will revise Chapter 6 accordingly. The exact language and the numbering used in the above text will be edited so that the text fits with the numbering used in Chapter 6.

## **COMMENTS FROM THE FLOOR**

### **Third-Party Accrediting Authorities**

The issue of contracting a third-party organization versus issuing a Memorandum of Understanding (MOU) for a third-party accrediting authority was raised in light of a new law passed by the State of California. Under this new law, California accrediting authorities are authorized to sign MOUs with third-party accreditors. Through these MOUs, any laboratory accredited by these third parties would be deemed accredited by the State of California. Comments were made from the floor that this should be explored by the USEPA. Because the California statutes had been recently promulgated and were unclear to those present at the Committee meeting, Dr. Bob Stephens was invited to address the Committee. Dr. Stephens described that the California law was driven by laboratory frustrations that, because of funding constraints, State accrediting agencies could not facilitate laboratory accreditations at the rate that was perceived as needed by the laboratories. However, Dr. Stephens indicated that it was his opinion that laboratories would prefer accreditation by a regulatory agency such as a State. He also believes that when NELAP is implemented, laboratories currently accredited by third-party organizations probably would want to become accredited by NELAP-recognized accrediting authorities.

As the California statute currently stands, standards for accrediting laboratories are set by the State. However, third party accrediting bodies are free to set standards higher than the standards set by the State. The California statute includes wording that allows the State to reconsider the procedures authorized by this new law when a national laboratory accreditation program is implemented. Currently, as the statute is written, it is Dr. Stephen's opinion that the State of California would not be eligible for NELAP recognition because third-party organizations would be the final decision makers for laboratory accreditation. This mechanism paralleled in the National Lead Laboratory Accreditation Program (NLLAP) where third-party organizations are accepted as accrediting authorities through MOUs with the USEPA. The Committee noted these comments but did not commit to further consideration of the third-party accrediting body concept embodied in the new California law.

### **Section 6.2 -- General Provisions**

Suggestions were made about identifying time frames and specifying "who," "what," and "where" throughout the sections.

#### **(a)**

The question of Indian tribes becoming accrediting authorities was raised, since each tribe is a sovereign nation. The NELAC Board of Directors has committed to address this issue.

#### **(c)(4) and (5)**

These sections may be reworded after resolution on reciprocity issues. Reciprocity was discussed at a joint meeting of the Accrediting Authority and the Policy Committee from 3:15-5:00 p.m. on February 4.

(j)

The question of the accreditation status of government laboratories that are organizational units within the same entity as an accrediting authority was raised. The DOD expressed a need to be a NELAP-recognized accrediting authority so that it can accredit its own laboratories. The Committee concurred that if freedom from conflict of interest could be demonstrated, DOD should be able to accredit their own facilities. The Committee will reconsider this item and endeavor to include provisions in Chapter 6 for eliminating conflict-of-interest issues, thereby providing a mechanism for DOD to accredit its own laboratories.

### **6.3.1 -- Written Application for NELAP Recognition**

(b)(16)

A question was raised about the applicability of the table in the application form requiring an accrediting authority to disclose how long it took for them to act on past applications for laboratory accreditation. This section was included to provide the information necessary to determine whether the accrediting authority has adequate resources to accredit laboratories within a reasonable time period as required by Section 6.3.3(d)(4).

### **Section 6.3.3 -- Application Technical Review by a NELAP Assessment Team**

(d)(6)

A question was raised to clarify the “performance evaluation system.” A concern was expressed that this requirement may not provide a true evaluation of an auditor’s performance when evaluating laboratories. The intent of this section was to ensure compliance with the ISO Guide 58 requirement for performance evaluation of auditors. The intent of this section was to ensure that performance evaluations for an accrediting authority’s site assessors would be carried out just as performance evaluations for other personnel within the agency. The Committee agreed to discuss this issue at a later date.

(d)(9)(D)

A question was raised about the use of the term “endorsement” in this section. ISO Guide 58 states that an accrediting authority’s logo cannot be used for product endorsement. The Committee wanted to be sure that NELAP accreditation did not imply endorsement of a particular laboratory. It was suggested that this section may more properly belong in Chapter 4, rather than Chapter 6.

(d)(10)(C)

A question was raised about the applicability of the phrase “include a statement that urges a client to verify NELAP-accredited laboratory’s accrediting status.” This was not discussed further.

(d)(13)

A suggestion was made to clarify requirements for quality systems for accrediting authorities, and include this as an Appendix or a Guidance Manual. The Committee said it would consider this suggestion.

## **Section 6.4.2 -- Conducting the On-Site Audit**

### **(a)(3)**

The Committee considered requiring (versus allowing an option for) the USEPA assessment team to accompany an accrediting authority's site assessors on an on-site audit of a laboratory. A comment was made that if an accrediting authority was required to allow the NELAP assessment team to accompany the accrediting authority's assessors on an on-site laboratory audit, satisfactory performance of assessors could be assured. Another commenter suggested that some accrediting authorities would choose their best assessors for the audit, and, thus, the resulting audit might not be a representative laboratory evaluation experience. Another comment was made that requiring a NELAP assessment team to accompany an accrediting authority's assessors on a site visit would ensure compliance with ISO Guide 58, and, thus, have international ramifications. A Committee member stated that a review of the assessors' report could provide an evaluation of the quality of the on-site audit of the laboratory.

It was noted that in the current drinking water laboratory accreditation program a number of States invite the USEPA to accompany their on-site assessors while auditing laboratories. Allowing the NELAP assessment team to observe laboratory assessors while auditing a laboratory was considered to be a critical element of ensuring credibility. This issue was not resolved. The Committee agreed to discuss further the degree of oversight of auditor performance needed to evaluate the quality of the audit functions carried out at a laboratory seeking NELAP accreditation.

## **COMMENTS FROM THE NELAP DIRECTOR**

### **Section 6.1 -- Introduction**

This section needs to be rewritten to clarify the following statement: "Since Chapter 6 requires all NELAP-recognized accrediting authorities to meet the requirements of the NELAC standards, Chapters one through six, all requirements of ISO/IEC Guide 58 will be met by a NELAP-recognized accrediting authority. The Committee agreed to discuss this issue at a later date.

### **Section 6.2 -- General Provisions**

#### **(j)**

When this section was drafted, the Committee had been informed that the USEPA would discontinue evaluation of laboratories when the NELAP is implemented. Thus, the prohibition against laboratories receiving accreditation from accrediting authorities which may be in the same agency or department as the laboratory seeking accreditation. Now, it appears the USEPA will accredit one laboratory in each state. The question of whether a State will have more than one accrediting authority was raised. Currently, as the chapter is written, the state can have multiple accrediting authorities. In the current drinking water program, USEPA evaluates one laboratory in the state and this laboratory evaluates all other laboratories. The NELAC Director said she will clarify the USEPA role in state laboratory accreditation in the near future. The Committee will revise this section after receiving clarification from the USEPA.

### **Section 6.3 -- Application for NELAP Recognition**

The section should be written so that it does not prevent an accrediting authority from being notified of a laboratory's violations in other accreditation programs. The Committee will consider this suggestion.

#### **6.3.1 -- Written Application for NELAP Recognition**

##### **(b)(15)**

A suggestion was made to eliminate references to the funding structure. This application item was included to satisfy ISO requirements. However, with Sections 6.3.1(b)(16) and 6.3.3(d)(4) in place, Section 6.3.1(b)(15) may not be necessary. The Committee will review this suggestion.

#### **6.4.3 -- On-Site Audit Reports**

##### **(h)**

The expectation that the USEPA will pay for the NELAP assessment team's travel costs for on-site audits of an accrediting authority should not be part of the standard. The Committee will review this section.

### **6.6 -- Certificate of Recognition for an Accrediting Authority**

##### **(b)(5)**

Requiring the signature of the NELAP assessment team members would slow the accreditation process by lengthening the time necessary to complete a certificate. The Committee will reconsider this requirement.

### **6.7 -- Requirements of the NELAP**

##### **(c) and (d)**

NELAC should not dictate to NELAP how NELAP carries out the details of managing its work. Possibly, these sections should be combined. NELAP will develop a database to track status of accrediting authorities. Very likely, the status of applications would be a subset of an overall data base covering all accrediting authorities. The Committee will review the wording of these sections.

### **6.8 -- Appealing Decisions to Deny or Revoke Accreditation**

##### **(b)(2) and (3)**

One commenter suggested that these two conflict-of-interest requirements be excluded because we do not want to eliminate employees of accrediting authorities from serving on the Appeal Board. The Committee agreed to revisit this issue. Further, the Committee will coordinate this section of Chapter 6 establishing an Appeal Board with the provisions of Chapter 1, Section 1.7.3 establishing the Accrediting Authority Review Board.



## **CONCLUSION**

Mr. Anderson concluded the meeting by thanking the Committee members and participants for helpful discussions and input for the revision of Chapter 6. Mr. Anderson indicated that he would work with Mr. Ted Coopwood, NELAC Executive Secretary, to schedule additional teleconferences so that the revisions of Chapter 6 would be completed by May 1, 1997, and the chapter would be ready for voting at the Third Annual NELAC Meeting to be held in July 1997.

## **NEXT TELECONFERENCE**

Mr. Anderson will inform the Committee of the dates of subsequent teleconferences as they are scheduled. The Committee expressed a desire to start weekly teleconferences in the near future so that it could complete its work well before May 1, 1997.

## **ADJOURNMENT**

The Committee concluded its general deliberations on Chapter 6 at 3:00 p.m. At 3:15 p.m., the Committee reconvened in Joint Session with the Program Policy and Structure Committee to discuss the issue of unconditional reciprocity among accrediting authorities. The record of that meeting is contained in a separate set of minutes.

**ACTION ITEMS**  
**Accrediting Authority Committee Meeting**  
**February 4, 1997**

Item No.	Action	Date Completed
1	Committee will solicit information from EPA relative to the USEPA's role in accrediting laboratories after NELAP is implemented.	February 5, 1997
2	Chapter 6 will be revised to accommodate USEPA's suggestions for the NELAP assessment team.	February 5, 1997
3	The Committee will examine the issue of using third party organizations for NELAP assessment team members.	
4	Section 6.2(j) will be revised after clarification from the USEPA about the number of accrediting authorities in a given State.	
5	The Committee will coordinate with the Chapter 1 Committee to rewrite requirements for the appeal board.	
6	The NELAC Board of Directors will address the issue of Indian tribes becoming accrediting authorities on a national scale.	
7	The Committee will rewrite Section 6.2(c)(1) using the terms "primary" and "secondary" accrediting authority terminology.	

**LIST OF COMMITTEE MEMBERS/MEETING PARTICIPANTS**  
**Accrediting Authority Committee Meeting**  
**February 4, 1997**

<b>Name</b>	<b>Affiliation</b>	<b>Phone/Fax/E-mail</b>
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**LIST OF COMMITTEE MEMBERS/MEETING PARTICIPANTS**  
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**February 4, 1997**

Invited Guests:

<b>Name</b>	<b>Affiliation</b>	<b>Phone/Fax/E-mail</b>
Carol Matting (substituting for Mary Ann Feige)		
Jeri Long	Illinois EPA, Division of Laboratories (Assistant to the Chair)	Tel: 217-782-6455 Fax: 217-524-0944 E-mail: epa6110@epa.state.il.us

**AGENDA**  
**Accrediting Authority Committee Meeting**  
**February 4, 1997**

**9:00 a.m. Eastern Standard Time**

Introductions

Ground Rules for Conduct of the Meeting

Roles of Participants

Overview of Chapter 6

Comments from NELAC Board of Directors

Credentials for the NELAP Assessment Team

**Unconditional Reciprocity -**

The major portion of discussions of reciprocity will be held in the joint meeting with the Policy and Structure Committee.

Comments from the floor

**3:00 p.m. -**  
**Adjourn**

**3:15 p.m. -**  
**Reconvene in Joint Session with the Program Policy and Structure Committee**  
**to discuss reciprocity.**